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08/765,623	12/27/96	RUEPP	M	062439.0107

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EXAMINER	
WITZ,J	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/06/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary	Application No. 08/765,623	Applicant(s) Ruepp
	Examiner Jean C. Witz	Group Art Unit 1651

☒ Responsive to communication(s) filed on *Feb 13, 1998*.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed February 13, 1998 have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4 remain rejected under 35 U.S.C. 103(a) as obvious over EP 347899 for the reasons of record.

Applicant states that "the Examiner constructs Applicants procedure out of unconnected teachings in the art, using the disclosure as a template. This is impermissible use of Applicant's disclosure." Applicant appears to be arguing that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning; however, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

As stated in the previous office action, the claims are drawn to a method for preparing crushed eggshells where the eggshells are washed with purified water with stirring at room temperature or elevated temperature, subjected to an autoclave treatment, dried and crushed to desired grain size. The crushed eggshells obtained from this method and the use of same for pharmaceutical applications are also claimed. The differences between the claims and the disclosure of the prior art are that an autoclave treatment is not distinctly disclosed, that the sterilizations step, i.e. autoclaving, is performed after cleaning and before drying and crushing, the reference does not specifically set forth that the eggshells are ground with a pin-disk mill and that the composition has a grain size distribution as set forth in claim 3.

The prior art clearly teaches that a crushed eggshell composition which is to be used pharmaceutically should be sterilized and it is further clear that the sterilization conditions disclosed by the prior art overlap the range of conditions considered within the scope of the process of autoclaving. It was noted by the Examiner, and has not been disputed by Applicant, that autoclaving is a well known and conventional sterilization process. Therefore, one of ordinary skill would have been motivated to select autoclaving as the sterilization process when practicing the disclosed method without engaging in undue experimentation and still have a reasonable expectation of success.

The only other difference is that the steps of the process have been rearranged in the claims. Applicant's mere statement that "there is no suggestion to prepare putamen ovi as disclosed and claimed in the present application, and Applicant's invention would not have been obvious over the '899 patent" fails to provide any reasons for said conclusion and is not persuasive in view of the Examiner's reasoning set forth in the previous office action and reproduced below.

Rearrangement of the steps is not seen as conferring patentability to the process as it appears merely a choice of convenience and ease to sterilize the eggshells in the uncrushed form prior to crushing because the finely crushed powder would be more difficult to work with in a steam autoclave due to clumping and dispersion. Finally, in absence of evidence to the contrary, the use of a pin-disk mill is conventional when crushing a substance and as the prior art teaches that the eggshells are crushed to a size of between 0.010 and 0.080 mm, it would appear that the referenced composition would have a similar distribution, which has not been shown to be critical to the formulation of the crushed eggshells into pharmaceutical compositions.

It is noted at page 3 of the specification, it appears that Applicant addresses the EP 847899 references, but identifies it as EP 847859. There, Applicant states that "the sterilization of egg-shell powder with dry air at 120°C for about 1 hour is not suitable for effecting a safe reduction of pathogenic germs and to counteract a loss in active ingredients due to too high temperatures. An increase in temperature at [greater than] 80°C, especially in the range of [greater than or equal to] 150°C, for more than 1 hour destroys the biologically present

carriers with membrane passage ability for an effective transport of minerals in compact and spongy substances. Following this thermal exposure, the egg-shell powder exhibits the biological effects of calcium carbonate with respect to the ^{45}Ca incorporation rate." However, Applicant at page 4 sets forth that "subsequent to the sterilization or optionally during the sterilization, the egg-shells are dried at elevated temperature" and at page 5, that "said germ count reduction or sterilization process is selected from autoclave treatment, hot air drying, tyndallization, treatment with ionizing or non-ionizing radiation, and gas sterilization." Finally, the specification states that the drying step may encompass sterilization "especially at a temperature of at least 150°C, for at least 3 hours". As Applicant applies the same conditions to the egg-shells that the reference does, it is not seen, absent a side-by-side comparison, how Applicant's eggshell powder is effective and the referenced eggshell powder is not.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (703) 308-3073.

6. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651.

May 5, 1998

JEAN C. WITZ
PRIMARY EXAMINER